UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: November 9, 2020

SUBJECT: Efficacy Review for Thymox Disinfectant Spray,
EPA Reg. No. 87742-1
DP Barcode: 459208
E-submission No. 54200

FROM: Kiran Verma
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Date Signed: November 9, 2020

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Date Signed: November 9, 2020

THRU: César E. Cordero
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)
Date Signed: November 9, 2020

TO: Demson Fuller, PM 32
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: LABORATORIE M2, Canada

Formulation from the Label:

Active Ingredient(s)	% by wt.
Thymol (present as) a component of thyme oil	0.23%
Other Ingredients	99.77%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Ready-to-Use Spray

Submission type: Label Amendment

Currently registered efficacy claim(s): Disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal), non-food contact sanitizer (hard non-porous and soft surfaces), food contact sanitizer

Requested action(s): Add disinfection claim against additional virus (SARS-CoV-2)

Documents considered in this review:

- Cover letter from applicant to EPA dated 8/26/2020
- Proposed label dated 8/26/2020
- Data Matrix (EPA Form 8570-35) dated 8/26/2020
- One efficacy study (MRID 51234902)
- One efficacy discussion (MRID 51234901)
- Confidential Statement of Formula (EPA Form 8670-4) dated 3/14/2012

II PROPOSED DIRECTIONS FOR USE

"For use on hard non-porous surfaces. Spray to [thoroughly][completely] wet the surface [to be disinfected] with [the][product][spray][Thymox® Disinfectant Spray] [(spot test to check compatibility [with the surface])]. Surfaces must remain wet for 2 minutes to eliminate bacteria [and] 3 minutes to eliminate fungi [,][,] 3 minutes to eliminate M. bovis BCG [TB] [and] 1 minute to eliminate viruses* [.] To disinfect Norovirus*, let stand for 4 minutes.[Allow to air dry.] [If desired, wipe dry.] {Fungal, M. bovis, and viral contact times will be listed if these organisms are on container label}{text will appear as necessary for organisms listed on the container label} [On food contact surfaces, no rinse is required][No rinse required, even on food contact surfaces] Food [products and packaging materials] must be removed or carefully protected prior to using this product. "

III STUDY SUMMARIES

1.	**MRID**	51234902		
Study Objective		Disinfectant-Virucidal		
Testing Lab; Lab Study ID		Microbac Laboratories, Inc.; 596-102		
Experimental Start Date		06/02/2020	**Study Completion Date:**	08/24/2020
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID 19 virus) (SARS-Related Coronavirus 2), USA-WA1/2020, BEI Resources, NR-52281		
Indicator Cell Culture		Vero E6 cells, (ATCC CRL-1586)		
Test Method		ASTM E1053-20		
Application Method		Spray until thoroughly wet using 4 pumps from a distance of 6-8 inches (2.0 mL).		

Test Substance Preparation	**Name/ID**	TMXPAE
	Lots ☐ **1** ☐ **2** ☒ **3**	TMXPAE-200326-1 (0.212% thymol), TMXPAE 200326-2 (0.213% thymol), TMXPAE-200326-3 (0.208% thymol)
	Preparation	Tested concentration: LCL Tested Dilution: *1:1.03 Diluent: Sterile DI water
Soil load		5% newborn calf serum
Carrier type, # per lot		Glass carrier, one per lot
Test conditions		Contact time: 55 seconds Temperature: 21°C Relative humidity: 34-35%
Neutralizer		MEM +10%NCS + 0.5% polysorbate-80 + 0.5% lecithin + 3% HEPES + 0.025N NaOH
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, etc.)		Amendments to the protocol: 1. Clarification that organic soil load was newborn calf serum. 2. Correction to Reference section, reference 4, 3. Correction to Health Canada references, 4. Correction to statement regarding Approval and signature of sponsor, 5. Clarification that the test substance is at ambient temperature, no pre-equilibration required. No protocol deviations occurred during this study.

*Lots No. TMXPAE-200326-1 and TMXPAE-200326-2 were diluted to bring testing concentration down to the LCL.

IV STUDY RESULTS

Disinfection – Virucidal Efficacy

MRID	Organism	Description	Results			Dried Virus Control (Log_{10} $TCID_{50}$/carrier)
			Lot TMXPAE-200326-01	**Lot** TMXPAE-200326-02	**Lot** TMXPAE-200326-03	
55 seconds, Diluted 1:1.3 in sterile DI water, 5% newborn calf serum						
51234902	Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID-19 Virus) (Strain USA-WA1/2020, Source: BEI Resources NR-52281)	10^{-2} dilution*	Cytotoxicity	Cytotoxicity	Cytotoxicity	5.85
		10^{-3} to 10^{-7} dilution*	Complete inactivation	Complete inactivation	Complete inactivation	
		Log_{10} $TCID_{50}$/carrier	≤2.10	≤2.10	≤2.10	
		Log Reduction	≥3.75	≥3.75	≥3.75	

*Dilution refers to the fold of dilution from the virus inoculum. Post neutralized sample was considered the 10^{-1} dilution.

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51234902	Disinfectant, virucidal	Hard non-porous surface	Liquid spray; Diluted 1:1.03	55 seconds	5% newborn calf serum	Sterile DI water	• Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV-2) (COVID 19 virus) (SARS-Related Coronavirus 2), USA-WA1/2020, BEI Resources, NR-52281	Yes

VI LABEL COMMENTS

Label Date/Identification Number: 08/26/2020

1. The proposed label claims that the product, Thymox Disinfectant Spray, when applied as a ready to use spray, is an effective disinfectant against Severe Acute Respiratory Syndrome-Related Coronavirus (SARS CoV-2) on visibly clean hard, non-porous surfaces for a 55 second contact time:

   These claims are **acceptable** as they are supported by the submitted data. It should be noted that the product was diluted in sterile purified water to develop the data submitted to support these claims.

2. Make the following changes to the proposed label:
   a. Throughout the label,
      i. Qualify "one step" claims that combine disinfection and cleaning with "when used according to disinfection directions. Some examples include but may not be limited to:
         1) "[For [Household][,] [Hospitals][,] [Institutional] [and] [Industrial] Use] [One-step Hospital Disinfectant Cleaner]"
         2) "[Thymox® Disinfectant Spray][This product is] [a] [one-step] [hospital] [disinfectant-cleaner]"
      ii. Qualify the term "eliminates" with 99.9% in all applicable disinfection claims.
      iii. Revise claims with excessive optional text to ensure these claims are coherent without the text marked as optional. An example includes:
         1) "[The efficacy of] [Thymox® Disinfectant Spray] [this product] [was shown in the presence of 5%organic serum] [.] [against][:] [is effective against] [kills][eliminates][:]"
      iv. Revise "*Trichophyton mentagrophytes"* to *"Trichophyton interdigitale*"
      v. Qualify each SARS CoV 2 claim to specify "on hard nonporous surfaces."
      vi. Revise the term "heavily soiled" with "visibly soiled."
   b. On page 1, remove the following statements: "[Respiratory illnesses attributable to Severe Acute Respiratory Syndrome ("SARS") are caused by a Coronavirus. Thymox® Disinfectant Spray is a broad-spectrum hard surface disinfectant that has been shown to be effective against other similar viruses.]" These statements are too broad and may be misleading. The agency limits these types of claims to off-label emerging viral pathogens claims only. On page 3, on "{TABLE 2}", qualify "[Stovetops]" with "Allow to adjust to room temperature before treatment/disinfectin".
   c. On page 6, delete the claim "[Disinfects in 3 minutes [or less] with [XX][16] EPA-registered kill claims]" as this claim may imply EPA endorsement.
   d. On page 6, revise the claim "Kills [Pandemic] SARS-CoV-2 Virus [formerly called SARS-nCoV]" to "Kills [COVID-19 Pandemic] SARS-CoV-2 Virus [formerly called SARS-nCoV]".
   e. On page 7, revise the statements:
      i. "[Thymox Disinfectant Spray] {insert product name} [effectively controls cross contamination on treated precleaned, hard, non-porous, inanimate surfaces.]" to "[Thymox Disinfectant Spray] {insert product name} [reduces cross contamination on treated precleaned, hard, non-porous, inanimate surfaces.]".
      ii. "[Prevents cross-contamination from treated surfaces]" with "[Reduces cross-contamination from treated surfaces]"

f. On page 7, delete the claim "[Help prevent the spread of diseases by proactive sanitation]". Efficacy claims against disease(es) are not supported by submitted efficacy data.

g. **Please revise the emerging viral pathogens statement on page 11 exactly as follows:**

"This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

-Enveloped Viruses

-Large Non-Enveloped Viruses

For an emerging viral pathogen that is a/an…	*…follow the directions for use for the following organisms on the label:*
Enveloped virus	Norovirus (Feline calicivirus surrogate)
Large, non-enveloped virus	Norovirus (Feline calicivirus surrogate)

Acceptable claim language:

[Product name] *has demonstrated effectiveness against viruses similar to* ***[name of emerging virus]*** *on hard,* ***non-porous surfaces****. Therefore,* ***[product name]*** *can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***Norovirus (Feline Calicivirus surrogate)*** *on* ***hard, non-porous surfaces****. Refer to the* ***[CDC or OIE]*** *website at* ***[pathogen-specific website address]*** *for additional information.*

[Name of illness/outbreak] *is caused by* ***[name of emerging virus]. [Product name]*** *kills similar viruses and therefore can be used against* ***[name of emerging virus]*** *when used in accordance with the directions for use against* ***Norovirus (Feline Calicivirus surrogate)*** *on* ***hard, non-porous surfaces****. Refer to the* ***[CDC or OIE]*** *website at* ***[website address]*** *for additional information.*"